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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,563	09/26/2003	Gerhardt Kumpe	06478.1494	8137

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT PAPER NUMBER

1653

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/670,563

Applicant(s)

KUMPE ET AL.

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 23 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12, 15 and 19 is/are rejected.
- 7) ☒ Claim(s) 11, 13, 20-24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This final action is in response to the Applicant's reply filed on 11/23/2005.

Claims 10-13, 15, and 19-24 are pending. Claim 14 has been cancelled. New claims 19-24 have been added.

The amendments to the claims filed on 11/23/2005 have been acknowledged.

This application claims foreign priority to GERMANY 10246125.2 filed on 10/01/2002.

All Objections and Rejections not mentioned in this office action are withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 15 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Claim 10 and 15 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a concentrate of VIII:C containing von Willebrand factors comprising subjecting a liquid comprising factor VIII:C and Willebrand factor to fractional precipitation using glycine and NaCl wherein the fractional concentration of glycine is 70-160 g/l and the fractional concentration of NaCl is 100-160 g/l, and does not reasonably provide enablement for all amino acids and all metal salts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification does not enable a person skilled in the art to which it pertains, or with which it is mostly connected, to make or use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are: 1) the nature of the invention, 2) the breadth of the claims, 3) the state of the prior art, 4) the predictability or lack thereof in the art, 5) the amount of direction or guidance present, 6) the presence or absence of working examples, 7) the quantity of experimentation needed, and 8) the level of the skill in the art.

1) the nature of the invention: the invention is a process for producing a concentrate of a factor VIII:C containing von Willebrand factor by fractional precipitation using amino acids and metal salt;

2) the breadth of the claims: claims are broad because they claim any amino acid and/or any alkali or alkaline metal salt that can be used in the process; further, more than one of that metals can be used, as referred to it in claim 10; further in claim 15, the conditions for the stabilization and pasteurization of the concentrate or the concentrate precursors should be provided;

3) the state of the prior art: the prior art discloses a similar method where glycine and NaCl are used in the process; pasteurization process is known, however chemical conditions for the stabilization of the concentrate or the concentrate precursor should be disclosed, since they are specific for the claims at issue;

4) the predictability or unpredictability of the art: claim 10 states that any amino acid and any alkali or alkaline metal salt (or combination of these) could be used in the method, and therefore, there could be many potential candidates of amino acids or metals, which are used in the method. Thus, the art is unpredictable, since undue experimentation would be necessary to characterize all possible amino acids and the metals claimed; further, the art is unpredictable for claim 15 also, since it would be an undue burden to characterize conditions for stabilization of the concentrate precursor;

5) the amount of direction or guidance present: in Experiment 1, the Applicants describe the use of glycine as an amino acid and NaCl as a salt; in the specification the conditions for stabilization of the concentrate precursor for claim 15 are not disclosed;

6) the presence or absence of working examples: the disclosure identifies only glycine and NaCl that are used in the instant method; there are no working examples for the stabilization of the concentrate precursor for claim 15;

7) the quantity of experimentation necessary: there would be an undue experimentation necessary to determine, and characterize all possible amino acids and metal salts that could be used in the method in claim 10; and there would be an undue experimentation to characterize the stabilization conditions of the concentrate precursor in claim 15;

8) the relative skill of those skilled in the art: the skill in the art is high, since similar method, which uses glycine and NaCl is known in the art.

In consideration of the *In re Wands* factors 1-8, it is apparent that there is undue experimentation necessary because of variability in prediction of the outcome that is not addressed by the present application disclosure, example, teachings, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue, rendering claim 10 subject to the scope of enablement rejection.

Applicants responded to the enablement rejection by providing different examples from the specification, for example, Example 3 that teaches precipitation of the vWF/FVIII:C fraction with glycine and NaCl, and state that the amino acid and alkali metal or alkaline earth metal salt can be easily tested and thus no undue experimentation is required. Further, the Applicants responded that the terms "pasteurizing" and "stabilizing" are adequately described and defined.

Examiner respectfully disagrees, and states that an undue experimentation would be required to test all claimed possible metals and amino acids, since experimentation data only provides glycine and NaCl, and no other experimental data is

presented. Also, an undue experimentation would be necessary to find out the conditions for stabilization of the concentrate precursor.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10 and 15 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because the value for the ratio "*greater than 1*" is not provided.

Applicants responded that because no maximum is given for the ratio of vWF:RcoF activity to vWF:Ag, does not mean that in light of the specification, one of ordinary skill in the art would not understand what is being claimed.

Examiner respectfully disagrees because a value greater than 1 is indefinite, since a reasonable range should be provided to make the claim definite.

In Claim 15, the word "*precursor*" is indefinite, since the structure or name of the precursor is not provided in the claim; also it is not clear how the process is stabilized and pasteurized (for example, claim lacks a temperature range, pH, and most appropriate time frame is missing from the claim).

Applicants responded that the claim is directed to a "process for producing a concentrate" and that a "precursor product" is any substance that precedes the final formation of the concentrate.

Examiner respectfully disagrees and requires further specification of the precursor in the claim, and additional information how the process is stabilized.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a concentrate of VIII:C containing von Willebrand factors comprising subjecting a liquid comprising factor VIII:C and Willebrand factor to fractional precipitation using glycine and NaCl wherein the fractional concentration of glycine is 70-160 g/l and the fractional concentration of NaCl is 100-160 g/l, and does not reasonably provide enablement for all amino acids and all

metal salts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification does not enable a person skilled in the art to which it pertains, or with which it is mostly connected, to make or use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are: 1) the nature of the invention, 2) the breadth of the claims, 3) the state of the prior art, 4) the predictability or lack thereof in the art, 5) the amount of direction or guidance present, 6) the presence or absence of working examples, 7) the quantity of experimentation needed, and 8) the level of the skill in the art.

1) the nature of the invention: the invention is a process for producing a concentrate of a factor VIII:C containing von Willebrand factor by fractional precipitation using amino acids and metal salt;

2) the breadth of the claims: claims are broad because they claim any amino acid and/or any alkali or alkaline metal salt that can be used in the process; further, more than one of that metals can be used, as referred to it in claim 19.

3) the state of the prior art: the prior art discloses a similar method where glycine and NaCl are used in the process;

4) the predictability or unpredictability of the art: claim 10 states that any amino acid and any alkali or alkaline metal salt (or combination of these) could be used in the

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method, and therefore, there could be many potential candidates of amino acids or metals, which are used in the method. Thus, the art is unpredictable, since undue experimentation would be necessary to characterize all possible amino acids and the metals claimed;

5) the amount of direction or guidance present: in Experiment 1, the Applicants describe the use of glycine as an amino acid and NaCl as a salt;

6) the presence or absence of working examples: the disclosure identifies only glycine and NaCl that are used in the instant method;

7) the quantity of experimentation necessary: there would be an undue experimentation necessary to determine, and characterize all possible amino acids and metal salts that could be used in the method;

8) the relative skill of those skilled in the art: the skill in the art is high, since similar method, which uses glycine and NaCl is known in the art.

In consideration of the *In re Wands* factors 1-8, it is apparent that there is undue experimentation necessary because of variability in prediction of the outcome that is not addressed by the present application disclosure, example, teachings, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue, rendering claim 19 subject to the scope of enablement rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite, since NaCl is an alkali metal salt, and not an alkaline earth metal salt, as it is claimed.

Objections to Claims

Claims 11, 13 and 20-24 are objected to because they depend from rejected independent claims, which are presently not allowed.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

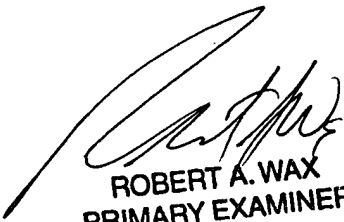
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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ROBERT A. WAX
PRIMARY EXAMINER